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**UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK**

MEDISIM, LTD

Plaintiff - Counterdefendant

v.

BESTMED, LLC

Defendant - Counterclaimant

Civil Action No.: 10-cv-2463 (SAS) (RLE)

Redacted Version

**BESTMED, LLC'S MEMORANDUM OF LAW IN OPPOSITION TO PLAINTIFF'S
MOTION TO DISQUALIFY BESTMED'S PROPOSED EXPERT, JACK GOLDBERG,
OR, IN THE ALTERNATIVE, STRIKE PORTIONS OF GOLDBERG'S REPORTS**

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All emphasis supplied unless otherwise noted

I. Introduction

The patent in suit relates to a device and method for measuring a person's temperature at a measurement site, calculating the temperature of the body under the skin, and then calculating the person's pulmonary artery temperature based on the first calculation. The '668 Patent purports to do so through use of sensor components known as thermistors, which produce electronic signals based on heat energy applied thereto. The signals are processed with a processing unit according to algorithms programmed thereon. BestMed's technical expert, Mr. Jack Goldberg, is more than qualified to offer his opinions to assist the trier of fact on the aforementioned technology.

Medisim's attempt to disqualify Goldberg and exclude portions of his well-reasoned report is disingenuous. Medisim's Motion is merely a reaction to BestMed's indication to the Court that it would move to strike the deficient reports of Medisim's experts, Dr. Lipson and Dr. Keegan. Medisim's intent is to distract from its own failure to submit proper expert reports. Such tactics should not be condoned in any way. Indeed, Medisim's arguments amount to mere displeasure with Goldberg's results, while raising no legitimate issues concerning Goldberg's methodology or analysis. Thus, Goldberg's opinions fully satisfy the requirements of Fed.R.Evid. 702. BestMed respectfully requests that this Court deny Medisim's Motion in its entirety.

II. Goldberg is Qualified to Testify on Relevant Technology

Medisim's challenge to Goldberg's credentials is ludicrous. Any review of Goldberg's *curriculum vitae* reveals decades of experience in thermometry and medical devices, which continue today. Goldberg's experience far surpasses Medisim's position on what constitutes a person of ordinary skill in the art: "a person having at least an undergraduate degree in engineering or physics, and at least 3 years of experience in digital thermometry." Ex. 1. His skills and background in thermometry also greatly exceed those of Medisim's expert, Dr. Lipson, who is but an academician with little or no actual experience in the subject technical field.

A. Goldberg's Education And Work Experience Afford Him The Requisite Specialized Knowledge and Expertise In The Relevant Field

A witness may be qualified as an expert if he possesses the necessary knowledge, skill, experience, or education. Fed.R.Evid. 702. Goldberg's education and work experience very clearly establish him as qualified to testify as an expert in thermometry, including electronic components, and the processing of generated electronic signals through the programmed computer processing unit that controls the thermometer.

Goldberg attended and graduated from the Massachusetts Institute of Technology ("M.I.T.") in 1973 with a Bachelor's degree in electrical engineering and computer science. Doc. 61, Ex. A at 94. He also obtained a Master's degree in electrical engineering and computer science, also from M.I.T, in 1978. Id. Indeed, Goldberg's M.I.T. Masters thesis was directed to firmware analysis and source code development. Goldberg Decl. ¶12. Goldberg was further selected to be a Senior Member of the Institute of Electrical and Electronics Engineers, and is an elected member of the Medicine and Biology, Signal Processing group. Doc. 61, Ex. A at 94.

Beyond his education, Goldberg's hands-on work experience further undoubtedly qualifies him as an expert in the relevant technology. Goldberg worked for over a decade as an engineer, project leader, an Engineering Manager, and later a Principal Engineer at IVAC Corporation. IVAC was a wholly owned subsidiary of Eli Lilly and Co. specializing in medical devices such as thermometers, blood pressure devices, and infusers. Goldberg developed medical products such as digital thermometers. Goldberg Decl. ¶4. Goldberg served as "technical leader in development of new infrared clinical thermometer and devised unique calibration methods." Doc. 61, Ex. A at 93. Indeed, Goldberg led his team to the development of IVAC's first infrared digital thermometer, the Core-Check model 2090, as well as the development of IVAC's next generation infrared thermometer. Goldberg Decl. ¶4. Goldberg also managed engineers responsible for IVAC's entire line of thermometers, including conductive thermometers. Id. As a

result of Goldberg's real-world experience and inventive contributions to IVAC's digital thermometers, he and a colleague were awarded U.S. Patent 5,150,969. Ex. 2.

Development of IVAC's thermometers involved the study and knowledge of human physiology, clinical testing, computer source code programming and circuit design. Goldberg Decl. ¶5. For example, Goldberg researched and developed algorithms for rapid detection of temperature with a conductive thermometer. He researched various methods of measuring temperature and developed manufacturing and testing apparatus for calibrating thermometers, including water bath testing and black body radiation testing. Id.

Medisim's characterization of Goldberg's direct and extensive experience in thermometry as "tangential" is pure sophistry. Goldberg's *curriculum vitae* highlights his impressive education and years of actual experience. By contrast, Medisim's technical expert, Dr. Lipson, fails to mention in his *CV* any experience in thermometry. Lipson offers no detail about what, if any, actual experience he has with thermometry other than a vague reference to consultant work on "patient thermometry" at IVAC; the same company where Goldberg was an Engineering Manager and Principal Engineer. Lipson fails to explain what work he actually did, if any.

B. Goldberg's Work and Knowledge in Thermometry, Medical Devices and Temperature Sensing Is Current

Goldberg continues his work in thermometry, medical devices and temperature sensing by way of product development projects and litigation support. Goldberg Decl. ¶6. Medisim's claim that Goldberg's experience in the field of thermometry is "stale" is specious.

Medisim absurdly asserts that Goldberg is "principally a professional expert witness." Goldberg's experience includes a plethora of product design projects over the past 15 years and includes "research and development for various medical, scientific and audio instrument manufacturers...." Several of such projects relate to thermometry and temperature sensing devices. Doc. 61, Ex. A at 92. Goldberg recently spearheaded several efforts in developing new

digital thermometers.¹ For example, Goldberg recently worked with a corporation to develop a new conductive digital thermometer. Goldberg, and corporation personnel, analyzed various thermometer and temperature measurement technologies and created strategy for development of a noninfringing design-around digital conductive thermometer. Goldberg Decl. ¶11.

In addition to his product development work, from 2002 to 2005, Goldberg served as a technical expert in *Exergen Corp. v. S.A.A.T. LTD. et al.* CA No. 01-11306-RGL (D. Mass.). This litigation involved infrared electronic thermometer technology and signal processing, and included an assertion of infringement of U.S. Patent 6,292,685.² Goldberg analyzed the '685 Patent, and studied prior art in the area of both infrared and conductive thermometry. Goldberg Decl. ¶7. He filed multiple expert reports and testified at trial about the relevant technology on behalf of S.A.A.T. Id. These efforts resulted in a final judgment of noninfringement and invalidity. *Exergen Corp. v. Wal-Mart Stores, Inc.*, 575 F. 3d 1312 (Fed.Cir. 2009).

Goldberg's experience further includes numerous other litigation support projects concerning thermometry and temperature sensing. Doc. 61, Ex. A at 96-101 and Goldberg Decl., Ex. A. Recently, Goldberg conducted a survey of conductive thermometry prior art, as well as preliminary noninfringement and invalidity analyses which included analysis of the thermometer and the uncovered thermometer patents. Goldberg Decl. ¶9.

C. Goldberg Possesses the Skill and Knowledge to Independently Analyze the FHT-1 Source Code

Medisim sheepishly argues in a footnote that Goldberg is not qualified to analyze the source code controlling the FHT-1 device. Doc. 60 at 11, n.5. Again, Medisim's claims fall flat.

Goldberg has substantial experience "with embedded firmware programming, LabView,

¹ Details regarding such projects are confidential. Goldberg Decl. ¶11.

² The '685 Patent is incorporated by reference into the patent in suit.

database, MatLab, and Visual Basic." Doc. 61, Ex. A at 92. The computer language C, which is the language used with the FHT-1 source code, is one of the most common computer languages, and was developed in the early 1970's. See, http://en.wikipedia.org/wiki/C_%28programming_language%29#Related_languages. Goldberg has programmed in C and other languages for the past 20 years. Goldberg Decl. ¶13. Goldberg took classes in C, has programmed extensively in C, can read and analyze C, as well as various computer languages based on C. Id. Indeed, his experience in the aforementioned higher level programming languages require interfacing with C. See e.g., <http://en.wikipedia.org/wiki/MATLAB>.

In his professional career, Goldberg wrote software source code for numerous devices, including electronic thermometers with a programmed microprocessor. Goldberg Decl. ¶14. In fact, Goldberg conducted software upgrades, re-wrote microprocessor code, and analyzed software source code in several programming languages. Id. at ¶12. Goldberg's experience extends past writing software code to managing entire software development teams. Id. To this day, Goldberg continues to write source code and manage firmware development on control devices. Moreover, as stated, Goldberg's M.I.T. Master's thesis involved firmware analysis. Id. Goldberg's practical experience also includes analyzing device-controlling source code in several litigation projects. Goldberg Decl., Ex. A at 3-4. For example, in the S.A.A.T. litigation *supra*, Goldberg based his noninfringement conclusion on review of the source code controlling the accused thermometers. Goldberg Decl. ¶17. Accordingly, Goldberg's analysis of the FHT-1 source code is backed with an experience-filled history of analyzing source code.

Goldberg's past and continuing experience provides him with vast knowledge of all types of thermometry, far beyond what Medisim's expert possesses. Indeed, until now, Goldberg's technical acumen has never been challenged, let alone has he been excluded as unqualified.

III. Goldberg's Invalidity Opinions Satisfy Rule 702

Medisim's Motion is merely a desperate attempt to resuscitate the '668 Patent from the clear and convincing evidence demonstrating its invalidity. In each of Goldberg's invalidity opinions, he applies the controlling law, including the Court's claim construction, and is fully qualified to do so. Goldberg's opinions are in sharp contrast to the baseless and legally flawed opinions of Medisim's technical expert.

A. Goldberg Independently Analyzed the FHT-1 Source Code

Medisim first revisits its argument, already rejected by this Court, that Goldberg should not be able to mention a report prepared by Mr. Gilliland. Gilliland's report discussed the source code for Medisim's FHT-1 sold prior to the critical date for the '668 Patent. As it did before, Medisim claims that Goldberg is merely acting as a conduit for Mr. Gilliland's opinions. Goldberg, however, independently analyzed the pre-critical date FHT-1 source code. This is plainly stated in his expert report.³ Several times, Goldberg indicates he has "reviewed the source code" and even pinpoints his review of "the source code of the calculation() subroutine (MED016849-856)." He clearly lists the FHT-1 software source code MED016836-898 and the EEPROM Map PARFHMW2 for NCHMV002 MED016833-35 as references he relied on in conducting this analysis. Goldberg's opinions based on his own analysis of the relevant evidence easily pass muster under Rule 702.

With regard to Goldberg's reference to the Gilliland Report, it is well-established that the facts forming the basis for an expert's opinions need not be admissible in evidence "[i]f of a type reasonably relied upon by experts in the particular field." Fed.R.Evid. 703; see also, *Louis Vuitton Malletier v. Dooney & Bourke, Inc.*, 525 F.Supp.2d 558, 665 (S.D.N.Y. 2007). Indeed,

³ There can be no serious doubt that Goldberg, who received both a bachelor's and master's degree in electrical engineering and computer science from M.I.T. possesses the knowledge and experience to analyze source code; and Medisim raises none.

this Court already rejected Medisim's "conduit" argument and found that Goldberg "is allowed to rely on other people's work, to some extent he does, but he says he relies on many things, and you're allowed to rely on other people as long as you yourself have expertise in the field and reviewed it yourself, and he says he did. So that's my thought on that one." Ex. 3 at 4.

Medisim's case law is inapt. Medisim's cases present scenarios where an expert relies on another's findings without familiarity with the underlying supporting facts. That is not the case here. Indeed the facts in *American Home Assurance Co. v. Merck & Co., Inc.*, 462 F.Supp.2d 435 (S.D.N.Y. 2006), closely parallel the facts here. In *American Home*, the court stated:

"[r]egarding American Home's objection to Jervis's testimony to the extent it relies on the report of Merck's prior insurance expert (the "Stellwag Report"), American Home's concern is overstated." ... "The cases cited by American Home ... take issue with an expert relying on or incorporating the findings of another expert without familiarity regarding the basis for that expert's findings. Here, Jervis reviewed all the underlying materials that informed the Stellwag Report and reached similar conclusions. Jervis's report then adds additional observations ... there is nothing improper about Jervis incorporating Stellwag's findings in his report."

American Home, 462 F. Supp. 2d at 448.

As with *American Home*, Goldberg reviewed the same underlying evidence, i.e., the source code and controller materials. So did Gilliland. Both reached similar conclusions. Goldberg then added additional observations, including his application of his and Gilliland's findings to the '668 Patent, and how the FHT-1 met the claimed limitations. See e.g.,

There is nothing improper about Goldberg's review and incorporation of Gilliland's findings.

Medisim's reliance on *Jung v. Neschis*, 2007 WL 5256966 (S.D.N.Y. 2007) is also misplaced. In *Jung*, the Court excluded a substitute expert's reliance on prior expert reports because of the substitute expert's unfamiliarity with the underlying facts. The Court deemed the reports prejudicial, given they were inadmissible due to the prior expert's incompetency and consisted of opinions formed largely based on the prior expert's "own observations." *Jung* 2007 WL 5256966 *16. The Court reasoned any reliance would "prejudice Defendants by ... subjecting them to the testimony of an expert witness they cannot cross-examine." *Id.*

There is no prejudice resulting from Goldberg's review of Gilliland's report. Medisim makes no such claim. Contrary to Medisim's counsel's initial representations to the Court⁴, Medisim received Gilliland's report together with the exhibits for Goldberg's opening expert report, as well as Gilliland's *curriculum vitae*. As indicated by this Court, Medisim and Dr. Lipson had the opportunity to read Gilliland's report, critique it and challenge it. Ex. 3 at 10. Medisim and Lipson, however, decided that they did not need to depose either Goldberg or Gilliland. Finally, as this Court notes, Medisim has full opportunity to cross-examine Goldberg's understanding of the FHT-1 source code and the Gilliland report. *Id.* at 11. Medisim has not done so. Goldberg is not relying on Gilliland's "own observations" but instead has made his own study of the underlying evidence. Accordingly, Medisim cannot be prejudiced by Goldberg's reference to the Gilliland report. *See American Home*, 462 F.Supp.2d at 448.

Medisim's hearsay arguments are also unavailing. Under FRE 703, "experts can testify to

⁴ "Court [to Medisim's counsel]: ... You misled me by making me think you knew nothing about what Gilliland did and who he was. First you said you didn't know his qualifications. It turns out you do. You have a report. I hadn't realized that. In the end I go back to saying he can say, I did the work, I have an opinion, here is my own expertise." Ex. 3 at 11.

opinions based on inadmissible evidence, including hearsay." *United States v. Mejia*, 545 F.3d 179, 197 (2nd Cir. 2008). Medisim makes no assertion that the Gilliland report is hearsay or inadmissible. Medisim also admits that "the use of such hearsay information from other experts is appropriate if the testifying expert forms his own opinions by applying his own experience and a reliable methodology ..." Doc. 60 at 9. In his report, Goldberg clearly applies his own experience and methodology.

Finally, Goldberg does not use the Gilliland report to merely bolster his findings. Bolstering occurs when a party will be prejudiced by an expert claiming that another well-credentialed non-testifying expert agrees with him. *United States v. Tran Trong Cuong*, 18 F.3d 1132, 1143 (4th Cir. 1994). The *Cuong* Court found it prejudicial for an expert to laud the fact that his results were "essentially the same" as the findings "of a general surgeon who is a close friend ... also a lawyer ...is well thought of in Northern Virginia" and who "has been president of the Medical Society." *Id.* Goldberg, however, makes no reference to Gilliland's qualifications, credentials or accolades. Indeed, this "is not a case of trying ... to bolster" Goldberg's conclusion "in order to make" Goldberg's "opinion more believable. *See United States v. Turner*, 592 F.3d 928, 933-944 (7th Cir. 2007). Rather, it is Goldberg exercising great care in his analysis, and refers to Gilliland's efforts merely to confirm his results.

The facts here are square with *Turner* where the Court allowed the expert statement that "I reviewed this report that Amanda Hanson generated for the analysis of the chunky material in Exhibits 1, 2, and 3... and came to the same conclusion based on the information provided that each of these items contained the same material ..." *Id.* at 934. Similarly, Goldberg reviewed Gilliland's work and came to the same conclusion. Goldberg does not purport to bolster his conclusions by claiming that the well-credentialed Gilliland agrees with him. Goldberg's reference to Gilliland's report was an exercise in prudence and cannot amount to bolstering.

The motivation behind Medisim's Motion on this issue appears to be based on the fact that its own expert failed or chose not to conduct any source code analysis. This failure to analyze the source code highlights the unreliability of Lipson's report. This is because it is only the instructions of the software program that carry out the algorithm that make a general purpose computer a special purpose machine for carrying out a particular function. *See WMS Gaming, Inc. v. Int'l Game Tech.*, 184 F.3d 1339, 1348-49 (Fed.Cir. 1999).

B. Goldberg's Non-Enablement and Undue Experimentation Opinions Are Based on a Correct Legal and Factual Framework

Medisim quibbles with Goldberg's invalidity opinions related to the failure of the '668 Patent specification to enable the full scope of the invention. Medisim's arguments boil down to a dispute regarding whether Goldberg's analysis was correct, not whether he has the knowledge and skill to review the relevant evidence. Such arguments pertain to the weight to be given to Goldberg's opinions, not whether he is qualified to render such opinions. Medisim's Motion on Goldberg's non-enablement opinions should be rejected for this reason alone.

Moreover, Goldberg's non-enablement opinions are based on a correct legal framework. Goldberg analyzes the relevant *Wands* factors in describing the extensive quantity and non-routine experimentation required to make a single sensor thermometer. *See In re Wands*, 858 F.2d 731, 736-37 (Fed.Cir. 1988). He further discusses the absence of working examples and guidance in the '668 specification of single sensor thermometers. Doc. 61, Ex. A at 28-29.

Medisim argues that in order to determine if undue experimentation is required to practice the full scope of invention, "one looks not only at the disclosures in the patent, but also information known in the art when the application was filed." Medisim offers no legal support, yet relies on its bald statement for its argument that one must scour the prior art to see what a person of ordinary skill in the art may have known. The law does not support Medisim's position.

The full scope of the claimed invention must be enabled. *Sitrick v. Dreamworks, LLC*,

516, F.3d 993, 999 (Fed.Cir. 2008). To be enabling, a specification need not disclose what is "well known in the art." *Genentech, Inc. v. Novo Nordisk, A/S*, 108 F.3d 1361, 1366 (Fed.Cir. 1997). "However, that general, oft-repeated statement is merely a rule of supplementation, not a substitute for a basic enabling disclosure. It means that the omission of **minor details** does not cause a specification to fail to meet the enablement requirement." *Id.* How one calculates deep tissue temperature "a body temperature under the skin" based on measurements taken at a skin surface temperature is hardly a "minor detail." Indeed, Medisim itself argues that the patentability of the '668 Patent depends on Yarden's purported recognition that to calculate the core body temperature one must first calculate a deep tissue temperature. Doc. 60 at 12. One simply cannot rely on the prior art to fill in the gaps in a specification's teachings.

"[W]hen there is no disclosure of any specific starting material or of any of the conditions under which a process can be carried out, undue experimentation is required; there is a failure to meet the enablement requirement that cannot be rectified by asserting that all the disclosure related to the process is within the skill of the art. **It is the specification, not the knowledge of one skilled in the art, that must supply the novel aspects of an invention in order to constitute adequate enablement.** *Genentech*, 108 F.3d at 1366.

A party cannot resort to "the knowledge of a person of ordinary skill to serve as a substitute for the missing information in the specification." *See Alza Corp. v Andrx Pharm.*, 603 F.3d 935, 941 (Fed.Cir. 2010). There is no requirement that Goldberg survey unrelated prior art. Goldberg's non-enablement analysis appropriately details the requisite undue experimentation necessary to practice the full scope of the '668 claims through his consideration of the relevant *Wands* factors. *See Amgen v. Chugai Pharm. Co.*, 927 F.2d 1200, 1213 (Fed.Cir. 1991)("it is not necessary that a court review all the *Wands* factors to find a disclosure enabling. They are illustrative, not mandatory. What is relevant depends on the facts ...").

Medisim next argues that Goldberg must conduct "empirical testing to determine the quantity and nature of the experimentation required...." Medisim's claim is again without legal

basis and simply makes no sense. Indeed, such a suggestion incredibly would require an actual undertaking of the undue experimentation to prove the undue experimentation asserted.

C. Goldberg Properly Applied the Court's Claim Construction in his Anticipation Invalidity Analysis

Unlike Lipson, Goldberg applies the Court's claim constructions throughout his expert reports, including his invalidity analysis. With its desperate arguments, Medisim hopes to distract the Court from its own expert's blatant departure from the Court's claim construction. Doc. 56 at 2-10. Lipson re-construes "deep tissue temperature" and "core body temperature" and in doing so, adapts claim constructions expressly rejected by the Court. See Id at 3-4 and 7-10.

Beyond Medisim's false accusations regarding Goldberg's application of the Court's claim constructions, Medisim again argues about whether Goldberg's conclusions are correct, not whether he is qualified to render an opinion. These arguments go only to the weight to be afforded Goldberg's opinions, not whether they are admissible.

1. Invalidity of the '668 Patent In View of the '452 Patent Is Based on the Court's Claim Construction for Core Body Temperature

Medisim argues that Goldberg did not apply the Court's claim construction for "core body temperature" in demonstrating that the prior art '452 Patent discloses a calculation of core body temperature. Medisim's claim is without merit.

The '452 Patent expressly states that the thermometer described therein calculates a "core body temperature." Doc. 61, Ex. A at 53. Medisim argues that one cannot assume that the "core body temperature" disclosed to in the '452 Patent is a pulmonary artery temperature, as "core body temperature" was construed by the Court. Doc. 60 at 15-16. The context of Goldberg's opinion indicates that the "core body temperature" in the '452 Patent is indeed pulmonary artery temperature. Goldberg first states that he analyzed the prior art based on the Court's claim construction. Doc. 61, Ex. A at 20. Moreover, he understands as a person of ordinary skill in the

art, that the "gold standard" and the most common meaning for core body temperature is the temperature of the blood in the pulmonary artery. Doc. 61, Ex. A at 72. Goldberg also notes a first temperature calculated by the '452 Patent's thermometer, namely "the equilibrium temperature determined for the surface of the patient," which is then corrected to the stated "core body temperature." Doc. 61, Ex. A at 53-54. Goldberg explains the '452 Patent's description for calculating core body temperature. Goldberg clearly explains that "FIG. 22 shows the steps used in the routine 222 for determining the value for an offset to be used in routine 224 for displaying the final calculation of the core body value (FIG. 23)... The '452 Patent thus discloses a two-step process which first calculates a deep tissue temperature and then corrects that deep tissue temperature to **determine** core body temperature."⁵

Medisim confusingly suggests that in order for Goldberg to have used the Court's claim construction, that he must literally substitute the words whenever he discusses "calculating." Such an argument is ridiculous. Goldberg actually uses the Court's language in explicitly describing how the '452 Patent "determines" the core body temperature. Doc. 61, Ex. A at 53-54. Accordingly, Goldberg applies the Court's claim construction in his invalidity analysis of the '452 Patent. Medisim's arguments, devoid of reason, have no merit.

2. Goldberg Applies The Court's Claim Construction As Part Of His Anticipation Opinions For The FHT-1

Similar to Medisim's complaints regarding Goldberg's opinions on the '452 Patent, Medisim devotes much of its arguments about the prior art FHT-1 device on whether Goldberg's

⁵ Medisim's argument is the ultimate case of the pot calling the kettle black. Medisim's supposed evidence of infringement hinges on the use of the term "core temperature" in K-Jump's 510(k). Doc. 56, Ex. 1 at 30-32. K-Jump's 510(k) never explains that its use of "core temperature" is pulmonary artery temperature. It does not. K-Jump calibrated its thermometers to oral temperature and never obtained clinical measurements for blood in the pulmonary artery. Doc. 61, Ex. B at 11, 21, 28-29 and 31. K-Jump's engineer also testified that the reference to "core temperature" did not mean pulmonary artery temperature. Doc. 61, Ex. B at 31.

conclusions are correct, not whether he is qualified to render an opinion. Again, such argument relates only to the weight of the evidence. Other than Medisim's disputes about Goldberg's conclusions, Medisim incorrectly argues that Goldberg failed to follow the Court's construction for "deep tissue temperature" or "calculating core body temperature" without a factual basis

a. The FHT-1 Device Calculates Core Temperature

Goldberg opined that the FHT-1 device sold prior to the critical date for the '668 Patent meets the "calculating a core body temperature" limitation. Unlike Medisim's expert, Goldberg followed the Court's claim construction.

The '668 Patent discloses a preferred embodiment where an algorithm is used by the processing unit to calculate the "core body temperature." Doc. 61, Ex. E at col. 9, ll. 15-63. As a matter of law, the scope of the claims is presumed to cover the preferred embodiment. *Vitronics Corp. v. Conceptiontronic, Inc.* 90 F.3d 1576, 1583-1584 (Fed.Cir. 1996). As such, to the extent that the evidence regarding the FHT-1 device corresponds to the preferred embodiment shown in the '668 Patent, that is proof of how the FHT-1, sold before the critical date, operated.

Goldberg states his "review of that software ... confirms that the FHT-1 product meets the "calculating a core body temperature" limitation for a number of reasons.

Goldberg's adherence to the Court's claim construction is also shown by his reliance on Medisim's admission that the FHT-1 calculated a "core body temperature." Prior to the claim construction Order, Medisim admitted that the FHT-1 displayed a "core body temperature."

RFA 38. Prior to May 31, 2005, Medisim offered for sale or sold in the United States a digital temple thermometer that included a display to display core body temperature.

RESPONSE: Medisim objects to the request on the ground that it incorporates language from the claims of the '668 Patent and thus is an effort to have Medisim disclose and apply its definition of a claim term. The Court has already promulgated a procedure and schedule for claim construction in this matter. Medisim further objects to the extent this request calls for a legal conclusion, and on grounds of undue burden. (See General Objection No. 11). Subject to and without waiving these objections, Medisim answers as follows based on its understanding of the claim terms: Admitted.

(Doc. 61, Ex. L). After the claim construction Order, Medisim opted not to supplement. Instead, Medisim held to its admission that the FHT-1 calculated "core body temperature."

Medisim now incredibly argues it "had no obligation to review the RFAs (sic) responses that had been expressly limited to Medisim's understanding of the claim terms for possible changes to the responses." Doc. 60 at 17. Medisim's assertion is without any support, and it is legally wrong. The Rules state: "a party is under a duty" to: (1) supplement ... its disclosures ... if the party learns that in some material respect the information disclosed is incomplete or incorrect" and (2) "to amend a prior response to [a] ... request for admission if the party learns that the response is in some material respect incomplete or incorrect" Fed.R.Civ.P. 26(e); see also *House v. Giant of Maryland LLC*, 232 F.R.D. 257 (E.D.Va. 2005)("A party who has answered a

Rule 36 request for admission has a duty to supplement his or her responses.").

In that several of Medisim's responses hinged on the meaning of claim terms, BestMed asked that:

"[t]o the extent these Requests include claim terminology and construction relating to the '668 Patent, BestMed requests supplementation of these Requests upon issuance of Judge Scheindlin's Claim Construction Order. Based on our discussions, it is our understanding that Medisim's responses to other Requests for Admission that included claims to be construed by the Court were based on Medisim's constructions. We request that after the Court issues its claim construction decision that Medisim review its responses and supplement if necessary."

(See Ex. 7). After the claim construction Order, BestMed reminded Medisim of its duty to supplement: "[t]o the extent necessary, please supplement responses to these Requests in accordance with the Court's Claim Construction Order. Any response to a Request containing claim terminology from the '668 Patent that is not supplemented will be taken as using the construction in the Court's Claim Construction Order." Ex. 8. Later BestMed stated, "[w]hereas the Court's claim construction renders many of Medisim's responses incomplete or incorrect, Medisim must supplement." Ex. 9. Medisim chose not to supplement, and thus made clear that it did not consider its responses to be incomplete or incorrect. Goldberg's reliance on Medisim's admission that the FHT-1 device calculated "core body temperature" is thus appropriate.

b. The FHT-1 Calculates Deep Tissue Temperature

As before, Medisim devotes almost its entire argument regarding Goldberg's opinions on whether the FHT-1 device calculated a deep tissue temperature to the weight of the evidence, not on whether Goldberg is qualified to render an opinion. Medisim's position that Goldberg's methodology lacks scientific basis, and therefore should be excluded is unfounded.

Goldberg based his conclusions on the source code for the FHT-1 device as well as Medisim's own admissions including the teachings of the '668 Patent itself, Medisim's documents describing the features of the FHT-1, as well as testimony by Mr. Yarden. Medisim does not

contend that any of such information is irrelevant to the operation of the FHT-1. Rather, Medisim merely disagrees with Goldberg's conclusions based on the evidence. Such disputes go to weight and can be addressed by way of cross-examination.

With regard to the source code for the FHT-1, Goldberg explains that he "reviewed the source code of the calculation() subroutine (MED016849-856) ..." and "an analysis of the FHT-1 software, as well as other evidence, all show that the FHT-1 product comprised 'a processing unit configured to ... calculate a deep tissue temperature...' Doc. 61, Ex. A at 42.

Goldberg's conclusion is further supported by Medisim's admission that its "R.A.T.E." technology is described in the '397 Patent. Ex. 5. Goldberg explains:

"[t]he '397 Patent discloses a device which calculates a deep tissue temperature according to measured heat flux and discloses an algorithm based on heat conduction physics for computing a deep tissue temperature ... The heat conduction physics described in the '397 Patent begins with the inventors' restatement of the well-understood one-dimensional conductive heat transfer equation with no heat sources: ... This equation basically states that the specific heat of a material times the rate of change of temperature is equal to the difference between the heat flux at the inlet and the outlet (the '397 Patent 1:66-67). An equivalent representation of the one-dimensional heat transfer equation appears in many textbooks ... The rest of the analysis at 1:65-2:53 follows from the basic equation, which is rewritten in finite difference equation form and simplified."

(Doc. 61, Ex. A at 12). He reasons: "because the FHT-1 product used R.A.T.E. technology and utilized the '397 heat flux algorithm, the FHT-1 product did calculate a deep tissue temperature, T_{avg} " as described in the '668 Patent. Doc. 61, Ex. A at 41. This is because the '668 Patent's teaching of calculating deep tissue temperature is the '397 Patent's algorithm.

In addition, Goldberg relied on Medisim's own documentation expressly touting the ability of the FHT-1 to calculate "deep tissue temperature." Ex. 6. Moreover, Goldberg relies on admissions by Yarden that the FHT-1 calculates what amounts to a deep tissue temperature.

Goldberg further explains, based on his education and experience in human monitoring, that the physics associated with this heat flow calculation is a calculation of a deep tissue temperature. Doc. 61, Ex. A at 12-13, 39 and 44-45. Again, while Medisim may disagree with Goldberg's analysis, reliance on physics cannot possibly fail to pass muster under Rule 702.

Medisim's argument that Goldberg equates Tavg and to be the same rings hollow, and merely another attempt to mislead this Court. Goldberg explains two separate analyses analysis of the '397 heat flux algorithm calculating "Tavg" as recited in the '668 Patent; and analysis of recited in the FHT-1 source code.

<u>Goldberg's Two Deep Tissue Temperature Analyses Related To "Tavg"</u>	
<i>Analysis of '397 Patent calculating "Tavg" as recited in the '668 Patent</i>	<i>Analysis of recited in the FHT-1 source code</i>
Medisim admits that the "R.A.T.E." technology is described in the '397 Patent as used in the FHT-1. Ex. 5.	Goldberg explains
Goldberg explains that "because the FHT-1 product used R.A.T.E. technology and utilized the '397 heat flux algorithm, the FHT-1 product did calculate deep tissue temperature, Tavg." Doc. 61, Ex. A at 41.	Goldberg further explains
Goldberg explains the '397 Patent heat flux algorithm is used in the '668 Patent to calculate deep tissue temperature, denoted as Tavg. Doc. 61, Ex. A at 41 and Doc. 61, Ex. E at col. 9, ll.5-63.	

Thus, the FHT-1 source code demonstrates a calculation of deep tissue temperature. Goldberg explains that "Tavg" represents is a deep tissue temperature in the '668 Patent. By contrast, the source code for the FHT-1 refers to _____ as representative of deep tissue temperature. He never equates these two _____ values as Medisim suggests.

IV. **Goldberg's Opinions Concerning Inequitable Conduct are Appropriate**

Medisim's arguments for excluding Goldberg's inequitable conduct analysis can be categorized either as specious misstatements of the law or a failure to read Goldberg's report.

Materiality in the context of an inequitable conduct analysis is a "but for" standard. *Therasense, Inc. v. Becton, Dickinson and Company*, 649 F.3d 1276, 1291 (Fed.Cir. 2011). As such, Goldberg's materiality analysis dovetails with his invalidity opinions.

Medisim does not contend that Goldberg's materiality determinations are incorrect. Rather, Medisim argues only that Goldberg failed to consider whether the prior art was cumulative, whether Goldberg's cited prior art was considered by the patent examiner, and whether Medisim has a duty of candor to the Patent Office. None of Medisim's quibbles actually relate to the question of "but for" materiality, which is the subject of Goldberg's opinions. Worse yet, Medisim's arguments are simply wrong as a matter of fact, law, or both.

Goldberg expressly states several times in his report that the '436 Patent and the '452 Patent are not cumulative to the prior art that was before the Examiner. "[T]he '436 Patent to Pompei is not **cumulative** of the art that was before the examiner during the prosecution of the '668 Patent because, unlike the prior art of record, the '436 Patent discloses a device and method for calculating a deep tissue temperature, and then correcting this first temperature for a core body temperature. Doc. 61, Ex. A at 18. "[T]he '452 Patent is not **cumulative** of the art that was before the examiner during the prosecution of the '668 Patent ..." Id. "As mentioned above, the '452 Patent is not **cumulative** of the art that was before the examiner during the prosecution of

the '668 Patent." Id at 42. "As mentioned above, the '436 Patent is not **cumulative** of the art that was before the examiner during the prosecution of the '668 Patent." Id at 68. Medisim apparently failed to actually read Goldberg's report before levying its false accusation.

With regard to Medisim's argument that its failure to disclose the pre-critical date sales of the FHT-1 device is somehow excused by its disclosure of a provisional application allegedly describing the FHT-1 is unavailing. First, the provisional application clearly does not describe the FHT-1 device. Rather, the provisional application is directed to "using IR radiation reading and use of disposing a contact surface in the form of a patch on the measured body surface." That is not a description of the conductive FHT-1 device. Second, the provisional application is not even prior art in that it was not "described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of the application for patent in the United States." 35 U.S.C. §102(b). Thus, even if the provisional application disclosed the FHT-1, the Examiner could not have applied it as prior art for invalidity purposes. Indeed, Medisim's claim that the provisional application disclosed the FHT-1 would only further demonstrate Medisim's intent to defraud the Patent Office. It would show Medisim disclosed the description of FHT-1, but concealed the facts that establish it as prior art.

Medisim's argument that Goldberg believes Medisim, the organization, has a duty to disclose is a red herring. Goldberg clearly states "that **applicants** for patents have a duty to disclose information known to them which is material to patentability to the PTO. It is my opinion that the **applicant of the '668 Patent** failed to disclose material information to the PTO of which he was aware ..." Doc. 61, Ex. A at 18-19. Indeed, Goldberg discusses emails from Ilan Vadai to Yona Sasson explicitly ordering the '436 Patent and the '452 Patent, thereby demonstrating the applicant's, Yarden's, knowledge of these patents. This Court already expressed that "... a trier of fact could draw an inference that because Vadai conducted a search, a

micropat search that revealed these two patents, and he did this all the time at Yarden's request and it was his practice to share the results with Yarden, I think a jury could draw an inference from that." Ex. 10. Medisim's argument should be given no weight.

Medisim argues, once again without precedent, that failure to consider an Examiner EAST Search History listing the '452 Smith and the '436 Pompei Patents as search terms are grounds for Goldberg's exclusion. This assertion is legally wrong. In order for a reference to be deemed to have been considered by the Patent Office, the patent examiner must list the particular reference and place his initials to indicate that he or she has considered the reference. *Bristol-Myers Squibb Company v. Rhone-Poulenc Rorer, Inc.*, 326 F.3d 1226, 1235-1236 (Fed.Cir. 2003); see also, MPEP § 717.05. In *Bristol Myers*, the Federal Circuit held that if an examiner had considered an article that appeared in a search report, he would have initialed and dated the search report and the article in keeping with regular performance of his duties. *Id.* Because the examiner did not initial and date the search report or article, there was no factual basis to support the position that the examiner considered the article. *Id.* A virtually identical situation exists here. The '452 Patent and the '436 Patent are found as search terms, but there is no indication that the examiner considered these references. If he had, under Patent Office normal procedures, he would have initialed and dated the search history listing or the references thereon. He did not. Thus, there is no evidence to support Medisim's contention.

V. Goldberg's Noninfringement Opinions Easily Pass Muster Under Rule 702

Medisim offers two bases for its argument for striking Goldberg's noninfringement opinion. First, Medisim argues that Goldberg failed to consider 510(k) submissions in his analysis. Medisim then argues that Goldberg did not follow the Court's claim construction for "calculating a core body temperature." Both of Medisim's arguments are utter nonsense and exemplify the absurdity of Medisim's entire Motion. Unlike Medisim's technical expert,

Goldberg actually examined the best evidence pertaining to the operation of the Accused Products in formulating his opinions, namely, the source code for the thermometers.

With regard to the 510(k) submissions, Goldberg specifically lists the K-Jump 510(k) submissions in his list of references. See Doc. 61, Ex. B at 55. Thus, Medisim's claim that Goldberg refused to consider such information is pure folly. Goldberg even expressly discussed the K-Jump 510(k) submissions and provides reasoning for why he did not consider them a reliable source of information regarding how the Accused Products actually functioned.

Goldberg explains that the primary purpose of 510(k) process is to demonstrate to the FDA that "a) a device which in intended to be marketed in the United States is substantially equivalent to a so-called "predicate" device and b) that the device intended to be marketed is **safe and effective**." Doc. 61, Ex. B at 17. In support, Goldberg cites Arthur K. Yellin's Article entitled "What are 510(k) clearance and pre-market approval:"

"The process is somewhat analogous to the "generic" drug concept in that Premarket Notification is used to obtain marketing clearance for a device that is "substantially equivalent" in safety and effectiveness to another lawfully marketed device or to a standard recognized by the FDA when used for the same intended purpose(s). **Note that the concept allows for technological advancement; the new device does not have to be manufactured from the same materials or perform its intended purpose using the same technology.** In order to be eligible for 510(k) clearance, the new device must exhibit roughly the same safety and effectiveness characteristics as the "predicate" device to which the new one is being compared." Doc. 61, Ex. B at 17-19.

Goldberg also explains, based on his own experience in filing 510(k) submissions, that the manufactured device does not have to operate as indicated in the 510(k). Doc. 61, Ex. B at 17-19.

Goldberg also considered the reliability of the K-Jump 510(k). Goldberg discussed the 510(k) with Mr. Emory Hsu, a K-Jump engineer, who confirmed that portions of the 2007 FDA 510(k) did not accurately reflect the operation of the Accused Products. Doc. 61, Ex. B at 26. Mr. Hsu explained at his deposition that the K-Jump 510(k)s include formulas and other descriptions that do not describe the operation of the Accused Products. Ex. 4 at 101-103. Mr. Hsu explained

that some formulas merely describe the derivational theory of development but are not implemented in the actual operation and functionality of the device. Id. Mr. Hsu further testified that the flow chart in the 510(k) submission did not accurately describe the functioning of the Accused Products, and that K-Jump never created a flow chart that "accurately depicts how either the 2200, 2201, or 2210 products work." Id at 141. Medisim was fully aware of Mr. Hsu's testimony about the 510(k) submissions and their lack of accuracy in describing the Accused Products. Goldberg also points to several other examples demonstrating the K-Jump 510(k)'s inaccurate description of the Accused Products. For example, the 2007 510(k) describes a thermometer having two temperature sensors, yet the Accused Products only have a single sensor. Doc. 61, Ex. B at 12. The 510(k) also describes a thermometer using a Sonix IC SN8P1909 microprocessor, whereas the Accused Products use different processors, namely, the SN8P1919 and the SN8P1927 processors. Doc. 61, Ex. B at 20 and 27. These differences are of little consequence to the FDA given it does not effect the product's safety but have significant implications in the litigation environment.

Given the purpose of a 510(k), the inaccuracies in K-Jump's 510(k), and lack of correspondence between the Accused Products and technical description in the 510(k)'s, Goldberg decided not to rely on them. This is because, in his opinion, the 510(k) is unreliable at best and irrelevant at worst. Doc. 61, Ex. B at 17-20. Whether Goldberg's decision was correct may be subjected to cross-examination, but in no event offers a reason to exclude his opinions.

Medisim insists Goldberg must rely on the K-Jump 510(k). This extraordinary position is ostensibly an attempt to conceal Lipson's fatal neglect to study the Accused Products's source code. Each claim requires a "processing unit" configured to determine "time-dependent parameters of temperature change" and calculate "deep tissue temperature" and "core body temperature." The processing unit of the Accused Products is a general purpose computer that

functions according to the instructions in the embedded source code. *See WMS Gaming*, 184 F.3d at 1348-49. Failure to analyze the source code makes it impossible to determine the calculations conducted at the processing unit and required by the claims. Accordingly, the only reliable methodology available is a review of the source code controlling the Accused Products a methodology Medisim and Dr. Lipson carelessly omit.

Medisim's attempt to paint Goldberg into a corner for relying on Medisim documents and other references in supporting his FHT-1 analysis is unavailing. Once again, Goldberg analyzes the source code controlling the FHT-1 device and determines the device practices the '668 claim limitations. Goldberg's further supports this conclusion by citing, *inter alia*, Medisim's admission that "[b]y utilizing the conductive R.A.T.E.TM technology, FHTTM thermometers measure deep tissues temperature." This supports Goldberg's source code analysis and is clearly appropriate. Accordingly, any attempt to preclude this portion of Goldberg's report lacks any merit.

Medisim's last-ditch attempt claims Goldberg fails to "analyze whether this ... oral equivalent temperature is an 'approximation' of pulmonary artery temperature." An oral temperature is a peripheral temperature and "there is a poor correlation between ... peripheral temperatures with the core body temperature." Doc. 45 at 33. Accordingly, an oral equivalent temperature cannot be an approximation of the temperature of blood in the pulmonary artery. Notwithstanding, Goldberg explains "conflating oral equivalent temperatures with core body temperature under the assertion that oral equivalent temperature is an approximation of core body temperature is contrary to any understanding in the field. Measured core body temperatures typically exceed correctly measured oral temperatures by about 0.4 C, and such a deviation would not fall constitute acceptable approximation." Doc. 61, Ex. B at 22-23. As such, Goldberg clearly explains why oral temperatures are not acceptable approximations of pulmonary artery temperatures. Once again, Medisim's disingenuous allegations are without merit.

VI. Conclusion

Goldberg's academic training in electrical engineering and computer science at the Massachusetts Institute of Technology, as well as his decades of hands-on experience in thermometry, including conductive thermometry, make him eminently well-qualified as an expert on the technical issues in this lawsuit. Goldberg's technical knowledge and experience will assist the trier of fact to understand the evidence to be presented in this lawsuit. Goldberg's expert reports are based on his own observation and analysis, is the product of established and well-known physical phenomena of heat conduction that have been reliably applied to documented facts in this case, and fully adhere to this Court's claim construction Order. In contradistinction, Medisim's attacks on Goldberg's report lack factual or legal support, are internally inconsistent, and overlook the Court's claim construction Order.

For the foregoing reasons, BestMed respectfully requests this Court deny Medisim's Motion to disqualify Mr. Goldberg or to strike his expert reports or any portion thereof.

Respectfully submitted,

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CERTIFICATE OF SERVICE

The undersigned hereby certifies that on December 20, 2011, a copy of the foregoing **BESTMED, LLC'S MEMORANDUM OF LAW IN OPPOSITION TO PLAINTIFF'S MOTION TO DISQUALIFY BESTMED'S PROPOSED EXPERT, JACK GOLDBERG, OR, IN THE ALTERNATIVE, STRIKE PORTIONS OF GOLDBERG'S REPORT** was electronically filed with the Court via ECF which thereby served an e-mail notice upon the attorneys listed below:

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